

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019766/S027

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW		1. ORGANIZATION DMEDP II, HFD-510	2. NDA NUMBER 19-766
3. NAME AND ADDRESS OF APPLICANT Merck Research Labs. PO Box 4 West Point PA 19486		4. SUPPLEMENT NUMBER, DATE S-027, 8-12-97	
5. PROPRIETARY NAME ZoCOR TM	6. NAME OF THE DRUG Simvastatin	7. AMENDMENTS, REPORT, DATE 11-13-97	
8. SUPPLEMENT PROVIDES FOR The addition of CVD event data to the labeling.			
9. PHARMACOLOGICAL CATEGORY antihypercholesteremic	10. HOW DISPENSED RX	11. RELATED IND, NDA, DMF ADDITIONAL INFORMATION	
12. DOSAGE FORM Tablets, oral	13. POTENCY 10, 20, 40 mg		
14. CHEMICAL NAME AND STRUCTURE See Chemistry Review #1			
15. COMMENTS ON CHANGES The sponsor requested to add clinical data on CVD in S-027. Because this data changed the Indications section of the PI, the sponsor was asked to provide an amendment requesting a waiver from the requirement to prepare an EA. The amendment of 11-13-97 provided a request for a categorical exclusion from the requirement to prepare an EA, based on 21 CFR 25.31(a), and the sponsor further noted that approval of this application will not increase the dosing levels or frequency of this drug. This request is acceptable.			
16. CONCLUSION AND RECOMMENDATION APPROVED ON CHANGES The request for a categorical exclusion to prepare an EA is acceptable. There are no chemistry issues involved in the labeling changes requested in S-027. This application is approvable based on chemistry issues.			
17. NAME WILLIAM K. BERLIN	18. REVIEWERS SIGNATURE /S/	19. DATE COMPLETED 3-30-98	
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17/S/ 3/30/98